

AS
Comments
Sub C1

lyoprotectant and [an] the antibody, wherein the molar ratio of lyoprotectant:antibody is 100-600 mole lyoprotectant:1 mole antibody.

Please cancel claim 27 without prejudice or disclaimer.

28. (Amended) The method of claim [27] 37 wherein the formulation is administered subcutaneously.

Sub B2
A3
Comments

29. (Amended) [A formulation comprising anti-HER2] The method of claim 37 wherein the formulation comprises the antibody in amount from about 5-40 mg/mL, sucrose or trehalose in an amount from about 10-100 mM, a buffer and a surfactant.

30. (Amended) The method of claim 29 wherein the formulation [of claim 29] further [comprising] comprises a bulking agent.

31. (Amended) The [formulation] method of claim 30 wherein the bulking agent is mannitol or glycine.

32. (Amended) The [formulation] method of claim 29 [which] wherein the formulation is lyophilized and stable at 30°C for at least 6 months.

33. (Amended) The [formulation] method of claim 32 [which is] wherein the formulation has been reconstituted with a diluent such that the [anti-HER2] antibody concentration in the reconstituted formulation is from about 10-30 mg/mL [, wherein] and the reconstituted formulation is stable at 2-8°C for at least about 30 days.

A3
cmcl.

34. (Amended) The [formulation] method of claim 33 wherein the diluent is bacteriostatic water for injection (BWFI) comprising an aromatic alcohol.

Please cancel claims 35-36 without prejudice or disclaimer.

Please add the following claims:

Sub B3

--37. (NEW) A method for treating a cancer selected from the group consisting of endometrial, lung, colon and bladder cancer in a human comprising administering a therapeutically effective amount of a formulation comprising an antibody which binds HER2 receptor to the human.

Sub B4

38. (NEW) The method of claim 37 wherein the cancer is endometrial cancer.

39. (NEW) The method of claim 37 wherein the cancer is lung cancer.

40. (NEW) The method of claim 37 wherein the cancer is colon cancer.

41. (NEW) The method of claim 37 wherein the cancer is bladder cancer.

Sub B5

42. (NEW) A method for treating ductal carcinoma *in situ* in a human comprising administering a therapeutically effective amount of a formulation comprising an antibody which binds HER2 receptor to the human.

*Sub
C5*

43. (NEW) The method of claim 42 wherein the formulation comprises a lyophilized mixture of a lyoprotectant and the antibody, wherein the molar ratio of lyoprotectant:antibody is 100-600 mole lyoprotectant:1 mole antibody.

44. (NEW) The method of claim 42 wherein the formulation is administered subcutaneously.

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C6*

*All
comcl.*

45. (NEW) The method of claim 42 wherein the formulation comprises the antibody in amount from about 5-40 mg/mL, sucrose or trehalose in an amount from about 10-100 mM, a buffer and a surfactant.

46. (NEW) The method of claim 45 wherein the formulation further comprises a bulking agent.

47. (NEW) The method of claim 46 wherein the bulking agent is mannitol or glycine.

48. (NEW) The method of claim 42 wherein the formulation is lyophilized and stable at 30°C for at least 6 months.

49. (NEW) The method of claim 48 wherein the formulation has been reconstituted with a diluent such that the antibody concentration in the reconstituted formulation is from about 10-30 mg/mL and the reconstituted formulation is stable at 2-8°C for at least about 30 days.

50. (NEW) The method of claim 49 wherein the diluent is bacteriostatic water for injection (BWFI) comprising an aromatic alcohol.--